

Lombart Lenses Ltd.
1215 Boissevain Ave.
Norfolk, VA 23507

For Soft-55 Vifilcon A Daily Wear Plastic Contact Lens:

Summary Of Safety And Effectiveness

The Soft-55 daily wear contact lens design is substantially equivalent to the designs of the predicate lens currently in commercial distribution (Softcon® Daily Wear lens). The Soft-55 lens also has light transmission, refractive index and physical characteristics comparable to the predicate Softcon® Daily Wear lens. Because the design is equivalent and the lens properties are equivalent and the manufacturing processes are equivalent, no new issues of safety or effectiveness are introduced by the Soft-55 lens. The Soft-55 daily wear lenses have the same intended use as the predicate Softcon® DW lens; they are fit on the cornea to correct the vision acuity of the patient. The lenses have identical indications, warnings, contra indications and produce the same effect on the eye. The Soft-55 lens is as safe and effective as the predicate device Softcon® Daily Wear lens.

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